

K062427
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VERTE-STACK® Spinal System
510(k) Summary
August 2006

I. **Company:** **Medtronic Sofamor Danek**
 1800 Pyramid Place
 Memphis, TN 38132
 (901) 396-3133

SEP 12 2006

Contact: **Edward S. Chin, D. Ph, MBA**
 Group Director, Regulatory and Clinical Affairs

II. **Proprietary Trade Name:** VERTE-STACK® Spinal System

III. **Classification Name/Product Code:** Spinal Intervertebral Body Fixation Orthosis
(21 CFR 888.3060)

IV. **Product Code:** MQP

V. **Product Description**

The VERTE-STACK® device consists of hemi-cylindrical center cages of various lengths and diameters, as well as hemi-cylindrical add on cages of various lengths, diameters and angulation. The assembled VERTE-STACK® device consists of three components (one hollow center cage, and two hollow add-on cages). The VERTE-STACK® components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

The design of the VERTE-STACK® device includes a variety of stackable components of different sizes and heights. The stackable components are designed to suit the individual patient pathology.

The VERTE-STACK® device may be used individually, or two or more may be stacked together in order to accommodate the individual anatomical requirements of the vertebral space created by the corpectomy.

The VERTE-STACK® Spinal System implant components are made of medical grade PEEK-OPTIMA LT1 along with a marker made from either Tantalum or titanium. Alternatively, VERTE-STACK® Spinal System may be manufactured from titanium alloy.

The VERTE-STACK® Spinal System must be used with additional anterior and/or posterior spinal instrumentation to augment stability. VERTE-STACK® constructs manufactured from PEEK may be used with stainless steel or titanium supplemental

fixation devices. Titanium VERTE-STACK® constructs may not be used with stainless steel supplemental fixation devices.

The purpose of this submission was to modify the wording of the VERTE-STACK® Spinal System package insert by removing certain contraindications and by including a NOTA BENE for potential factors to consider with regards to when not to use this device. The rewording of the document makes it more consistent with that of the package insert for the CD HORIZON® Spinal System, which may be used as the supplemental fixation device for the VERTE-STACK® device.

V. Indications

The VERTE-STACK® Spinal System is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The VERTE-STACK® Spinal System is to be used with supplemental fixation. Specifically, the VERTE-STACK® device is to be used with the Medtronic Sofamor Danek ZPLATE II Anterior Fixation System, the DYNALOK™ CLASSIC Spinal System, the VANTAGE™ Anterior Fixation System, the TSRH® Spinal System, the CD HORIZON® Spinal System, the GDLH® Spinal System and/or their successors. Additionally, the VERTE-STACK® device is intended to be used with bone graft.

VI. Substantial Equivalence

Documentation was provided which demonstrated that the subject VERTE-STACK® Spinal System components are substantially equivalent to the previously cleared VERTE-STACK® Spinal System components most recently cleared in K061938, SE 08/15/2006; and to the CD HORIZON® Spinal System, as cleared in K061304, SE 07/18/2006.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medtronic Sofamor Danek
% Edward S. Chin D. Ph, MBA
Group Director, Regulatory and Clinical Affairs
1800 Pyramid Place
Memphis, Tennessee 38132

SEP 12 2006

Re: K062427
Trade/Device Name: VERTE-STACK[®] Spinal System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: August 17, 2006
Received: August 18, 2006

Dear Mr. Chin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, and Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

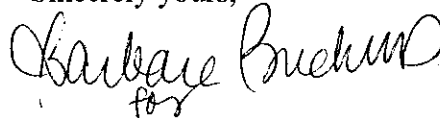
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Edward S. Chin D. Ph, MBA

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a small "for" written below it.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1062427

August 2006

510(k) Number (if known): _____

Device Name: VERTE-STACK® Spinal System**Indications for Use:**

The VERTE-STACK® Spinal System is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The VERTE-STACK® Spinal System is to be used with supplemental fixation. Specifically, the VERTE-STACK® device is to be used with the Medtronic Sofamor Danek ZPLATE II Anterior Fixation System, DYNALOK™ CLASSIC Spinal System, the VANTAGE™ Anterior Fixation System, TSRH® Spinal System, CD HORIZON® Spinal System, the GDLH® Spinal System, or their successors. Additionally, the VERTE-STACK® device is intended to be used with bone graft.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**510(k) Number 1062427